DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 09, 2017

Rhythm Xience, Inc.
c/o Mark Job
Regulatory Technology Services LLC
1394 25th Street NW
Buffalo, MN 55313

Re: K171081
Trade/Device Name: Guider Catheter Introducer
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: April 7, 2017
Received: April 11, 2017

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*

K171081

Device Name

GUIDER™ CATHETER INTRODUCER

Indications for Use *(Describe)*

The RXI Guider ™ Catheter Introducer is indicated for introducing various cardiovascular catheters into the heart, including the left side of the heart through the interatrial septum.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

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## 5.0 510(k) SUMMARY AS REQUIRED BY 21 CFR 807.92

510(k) Number: K 171081 or TBD [X]

Date Prepared: March 22, 2017

**Table 5.1 SUBMITTER INFORMATION**

| | |
|---|---|
| Submitter: Rhythm Xience Inc.<br>Street Address: 10025 Valley View Road<br>Suite 130<br>Eden Prairie, MN 55344<br><br>Establishment registration: awaiting 510(k) clearance prior to initial registration/listing | Contact Person: Jim Hassett<br><br>Phone: 952-479-7903<br>Email: jimhassett@rhythm-xience.com |

**Table 5.2 DEVICE INFORMATION**

| | |
|---|---|
| Trade Name | Guider™ Catheter Introducer |
| Common Name | Catheter Introducer |
| Classification Name | Introducer, Catheter |
| Regulation /Product Code | 21 CFR 870.1340 |
| Product Code | DYB |
| Regulatory Classification: | Class II |
| Device Panel: | Cardiovascular |

The RXI Guider Catheter Introducer is substantially equivalent to the previously-cleared, St. Jude Medical (SJM) Swartz™ Braided Transseptal Guiding Introducer, K052644.

**Table 5.3 PREDICATE DEVICE**

| **Predicate Device** | **Manufacturer** | **FDA 510(k)** |
|---|---|---|
| Swartz™ Braided Transseptal Guiding Introducer | St. Jude Medical, Inc. | K052644 |

### 5.1 Device Description

The Guider Catheter Introducer set contains a fixed-curve introducer, integrated vessel dilator/transseptal needle (component branded as Lancer™), guidewire, and ECG adapter cable. The set is designed to facilitate vascular access to the heart and then provide catheter positioning within the cardiac anatomy (see **Figure 5.1**).

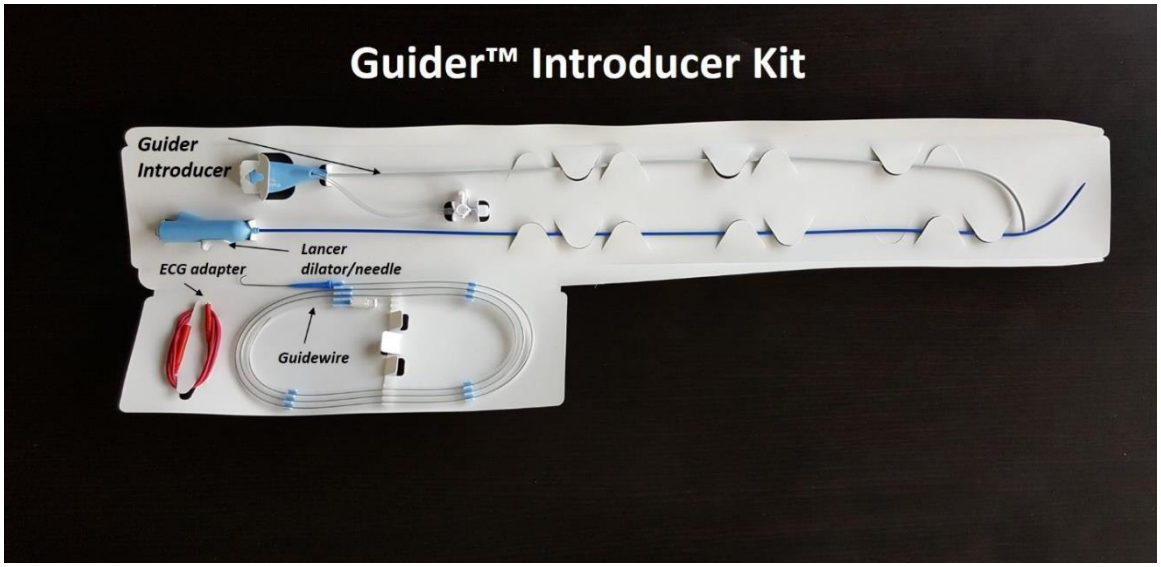


**Figure 5.1** Guider Introducer Set

The Guider Catheter Introducer is an elongated shaft with central lumen capable of accepting the Lancer dilator/needle as well as various cardiac catheters. The Guider handle is also fitted with a hemostasis valve to minimize blood loss during catheter introduction, and/or exchange, as well as a sideport with 3-way stopcock to allow blood aspiration, fluid infusion, and pressure monitoring. The introducer shaft features distal side holes to facilitate aspiration and prevent cavitation plus an embedded platinum radiopaque tip marker to facilitate fluoroscopic visualization (see **Figure 5.2** and **Figure 5.3**).

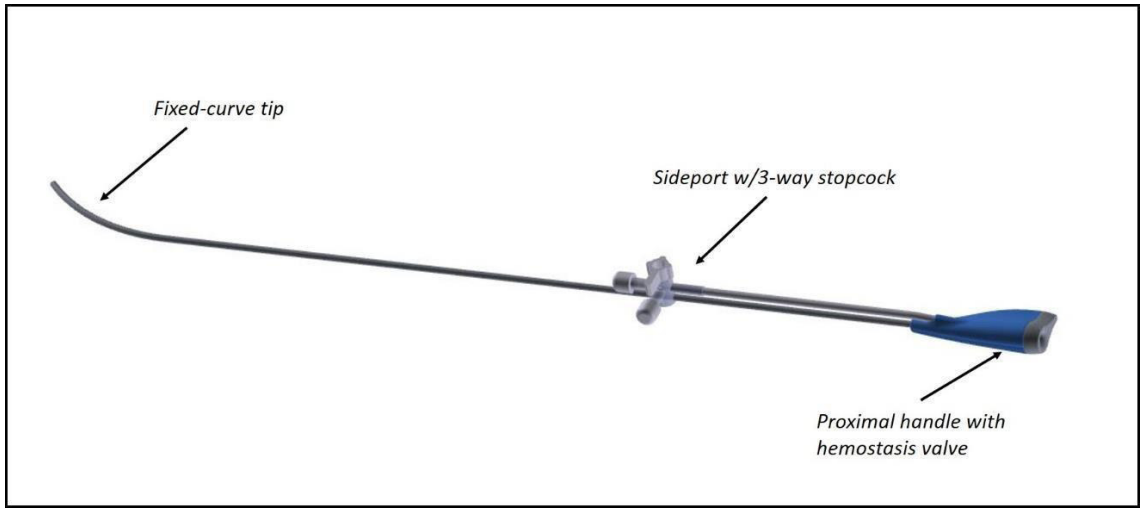


**Figure 5.2** Guider Catheter Introducer

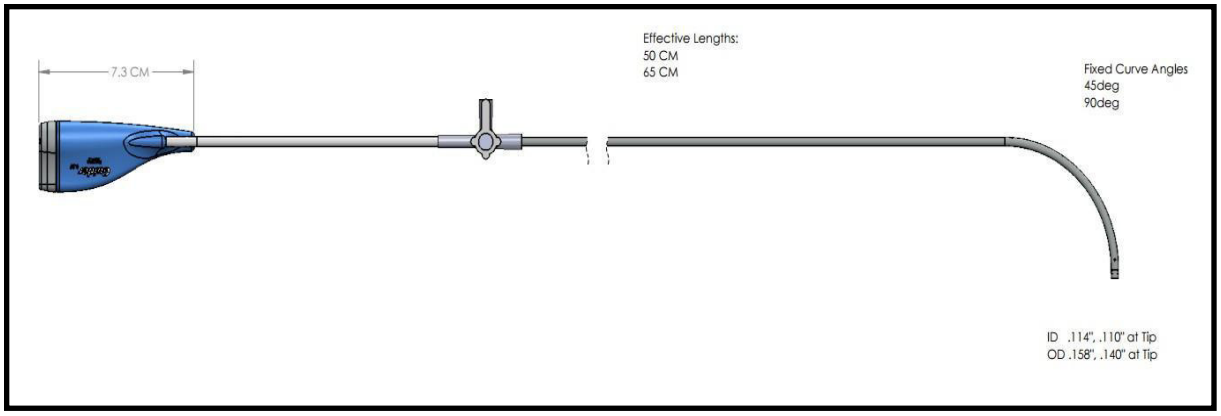


**Figure 5.3** Guider Dimensional Drawing

The set includes the following accessories (see **Figure 5.4**):

- Lancer Integrated Dilator/Needle
- J-Tip Guidewire
- ECG Adapter

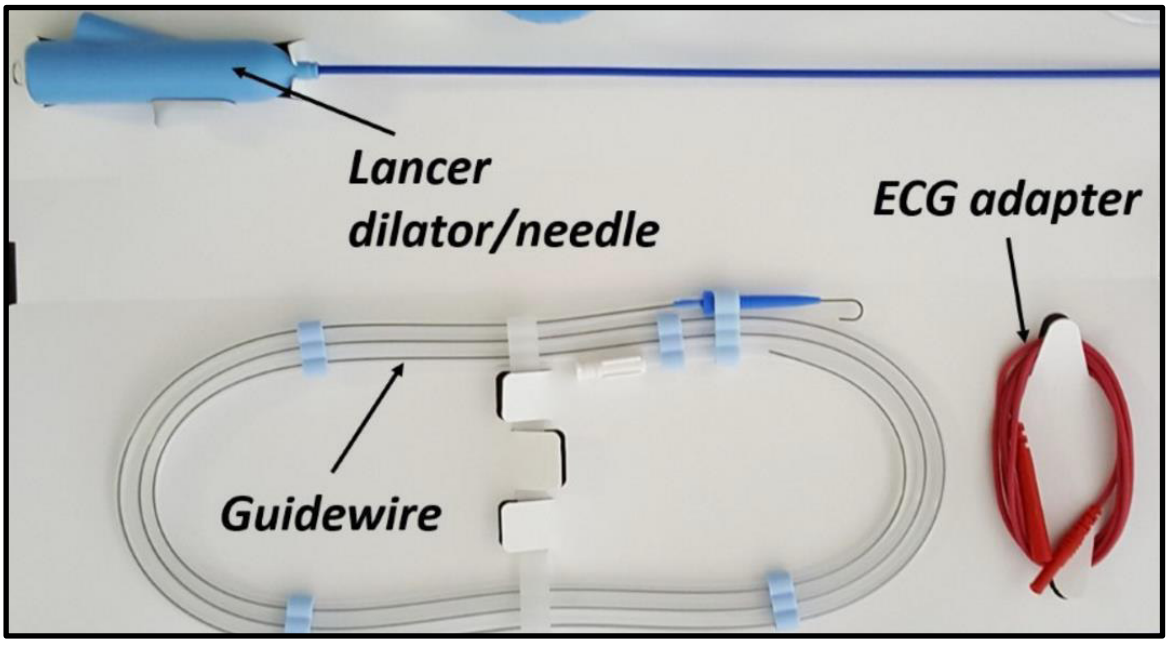


**Figure 5.4** Guider Accessories

The Lancer integrated dilator/needle combines a dilator and transseptal needle into a single component (see **Figures 5.5** - **5.7**). The needle is used to puncture the interatrial septum to gain access to the left atrium similar to the St. Jude Medical BRK™ Transseptal Needle (K072278). The Lancer consists of an elongated shaft with a tapered tip and central lumen to track over a guidewire in a similar fashion to conventional dilators. The lumen of the Lancer is fitted with a hollow stainless steel transseptal needle and both the shaft and needle are connected to the same proximal handle. The needle lumen will accept guidewire sizes up to 0.032 inches in diameter. Inside the Lancer handle, the needle is affixed to a spring-tensioned actuator that prevents needle extension until the operator purposely advances the needle via a slider button located on the outer surface of the handle. The proximal handle is fitted with a Luer connector to gain access to the central lumen of the needle. The handle is also fitted with an electrical connector to monitor an ECG from the needle while in the heart, utilizing the ECG adapter cable. This is done in a similar manner as pericardiocentesis kits whereby electrocardiograms are monitored from the needle during use (reference **Figure 5.8**, Boston Scientific PeriVac Pericardiocentesis Kit, K032050).

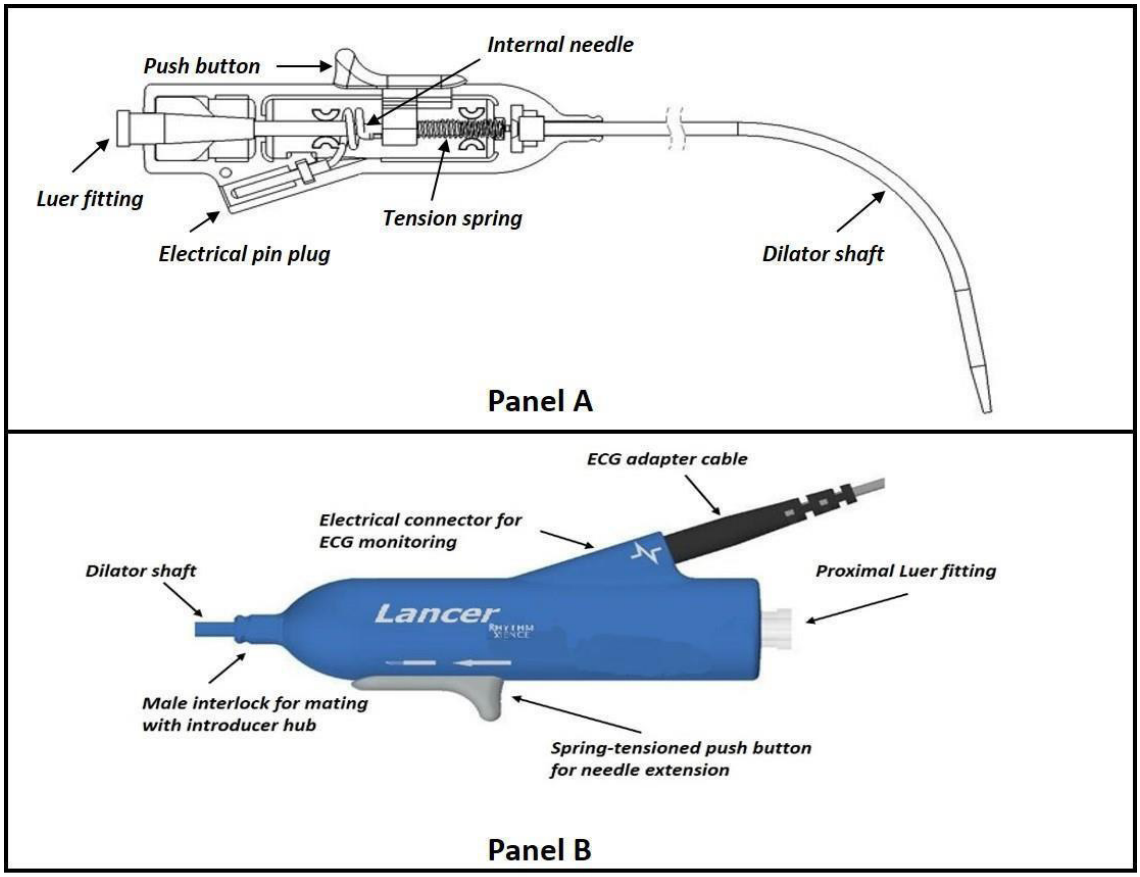


**Figure 5.5 Lancer integrated dilator/needle. Panel A** is a profile technical drawing depicting the internal components of the handle. **Panel B** illustrates the handle features.

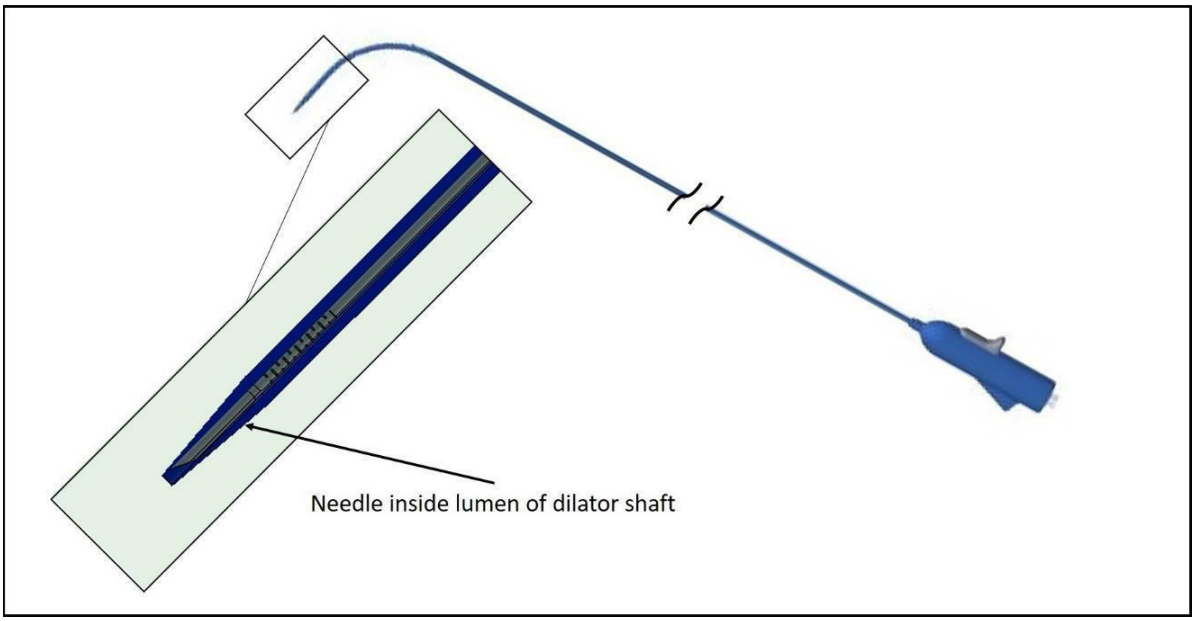


**Figure 5.6** Lancer with inset depicting internal needle in baseline retracted position

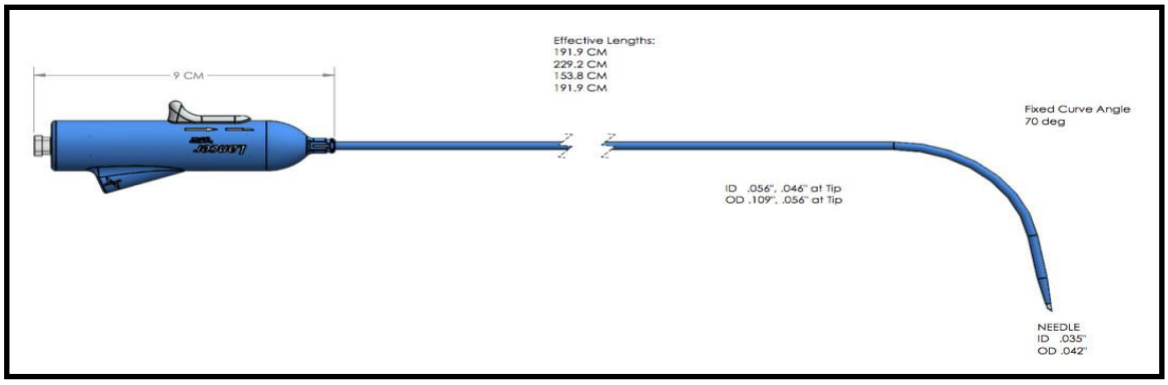


**Figure 5.7** Lancer Dimensional Drawing

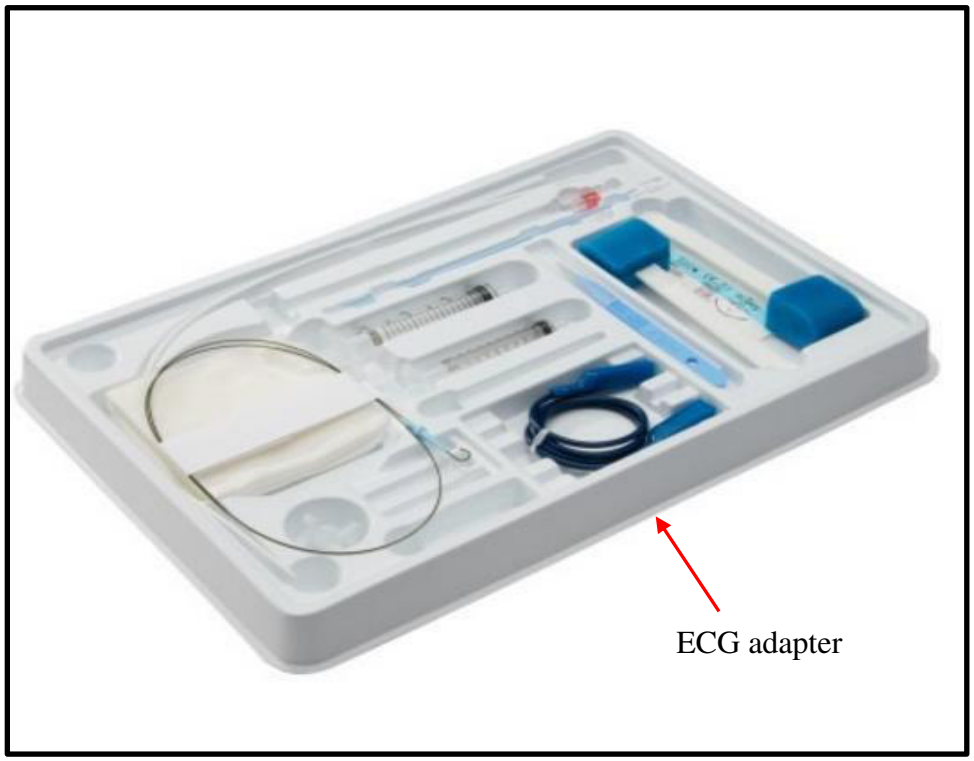


**Figure 5.8** Boston Scientific PeriVac Pericardiocentesis Kit

The distal end of the Lancer handle and the proximal end of the Guider handle are designed with male/female surfaces to mate the components together in a snap-fit closure (see **Figure 5.9)**.

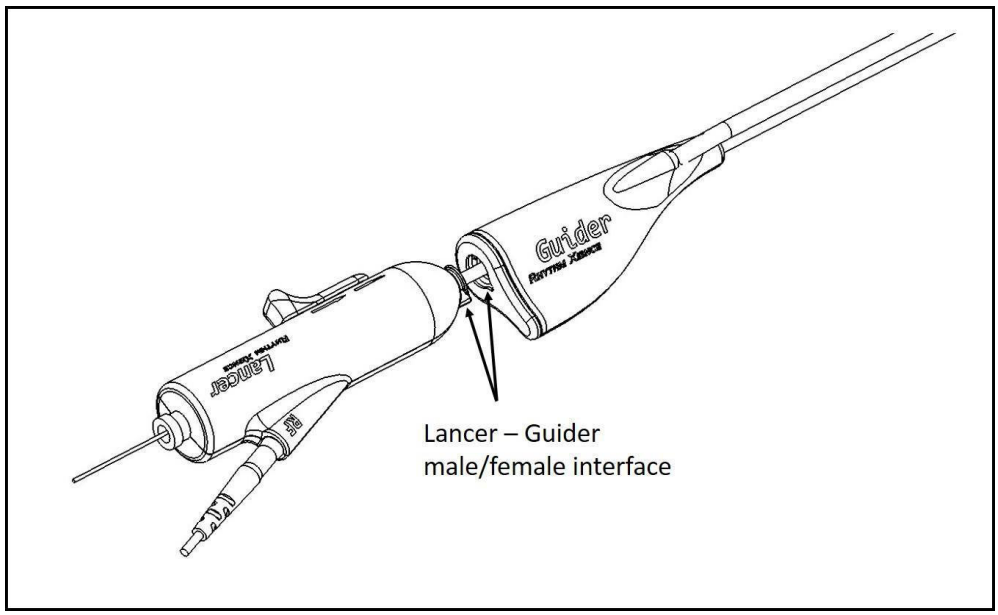


**Figure 5.9** Guider to Lancer mating feature

The guidewire included in the set is manufactured by Lake Region Medical (K935170) and is supplied in a polypropylene retainer coil with a J-straightener and Luer fitting. The Luer fitting is compliant to ISO 594-1 and ISO 594-2. The ECG adapter cable included is manufactured by Bioconnect (RF Industries, Inc.), is one (1) meter long, and has male/female DIN 0.080 inch touch- proof connectors on the ends.

The patient-contacting materials used in the Guider Catheter Introducer set are listed in **Table 5.4**. A detailed listing of all materials used in the set is provided in the submission.

**Table 5.4** Guider Catheter Introducer set List of Materials

| Component | Materials |
|---|---|
| **Guider** | |
| Shaft | Pebax (6333, 3533) with Barium Sulfate and gray colorant<br>Polytetrafluoroethylene (PTFE)<br>Polyvinyl chloride (PVC)<br>Ethyl Cyanoacrylate<br>Polycarbonate, High Density Polyethylene (HDPE)<br>Acrylic UV Curable<br>Polypropylene, White<br>Siloxane Lubricant (Nusil MED-4162)<br>304 Stainless Steel<br>Platinum |
| Sideport | Polycarbonate, High Density Polyethylene (HDPE)<br>Polyvinyl Chloride (PVC)<br>UV Adhesive |
| Hemostasis Valve Assembly | Polyisoprene<br>Buna-N, Durometer Shore A50<br>304 Stainless Steel<br>Acrylonitrile butadiene styrene (ABS) with white colorant<br>Acrylic UV Curable<br>Silicone, Nusil Med-420<br>Ethyl Cyanoacrylate |
| **Lancer Dilator/Needle** | |
| Shaft | Polyethylene Hexene Copolymer<br>Ethylene Homopolymer<br>Barium Sulfate with blue colorant |
| Hypotube | 304 Stainless Steel |
| Needle | 304 Stainless Steel |
| Luer Fitting | Polycarbonate |
| **Guidewire** | |
| Guidewire | Polytetrafluoroethylene (PTFE) coated stainless steel |

There are four (4) models of the Guider Catheter Introducer set based on useable length and/or degree of tip curvature (the Lancer component is length-matched to the Guider introducer). All models have an inner diameter of 8.5 French. These include:

1. L1 (45°), 50 cm, 8.5 French
2. L1 (45°), 65 cm, 8.5 French
3. L2 (90°), 50 cm, 8.5 French
4. L2 (90°), 65 cm, 8.5 French

The Guider Catheter Introducers are shipped sterile in sealed Tyvek® pouches placed inside a cardboard shelf box and labeled single use only. Sterilization is by ethylene oxide.

### 5.2 Indications for Use

The Guider Catheter Introducer is indicated for introducing various cardiovascular catheters into the heart, including the left side of the heart through the interatrial septum.

### 5.3 Summary of Testing

The Guider Catheter Introducer set underwent the tests listed in **Table 5.5**. Testing was conducted at three different time intervals:

1) Baseline – 2x sterilization, environmental conditioning and distribution simulation (T=0)
2) Accelerated aging – 2x sterilization and 12-month accelerated aging (T=12aa)
3) Real-time aging – 2x sterilization and 12-month real-time aging (T=12rt).

The testing was performed by the following vendors and locations:

- Biocompatibility testing and an animal study was performed at American Preclinical Services, Inc., located in Minneapolis, MN.
- Sterilization testing was performed by Steris Isomedix, located in Minneapolis, MN.
- Environmental Conditioning, Distribution Simulation Testing, Accelerated Aging, Peel Strength and Bubble Leak Testing were performed by Distribution Dynamic Labs, Inc. (DDL) in Eden Prairie, MN.
- Particulate testing was performed at Nelson Labs located in Salt Lake City, UT.
- Electrical testing was performed at Medical Equipment Compliance Associates, LLC. (MECA) located in Franklin, WI.
- All other testing was performed internally at CRI-Devices in Maple Grove, MN.

**Table 5.5 SUMMARY OF TESTING**

| Test Type | Test Name |
|---|---|
| Biocompatibility | Hemocompatibility<br>Cytotoxicity<br>Sensitization<br>Irritation<br>Pyrogenicity<br>Systemic Toxicity<br>Thrombogenicity |
| Sterilization Validation | LAL<br>Bioburden<br>EO residuals |
| Packaging | Environmental Conditioning<br>Distribution Simulation –Post Environmental Conditioning<br>Visual Evaluation - Post Environmental Conditioning/ Distribution Simulation<br>Bubble Test - Post Environmental Conditioning/ Distribution Simulation/ Visual Evaluation<br>Seal Strength- Post Environmental Conditioning/ Distribution Simulation/ Visual Evaluation/ Bubble Leak |
| Shelf Life | 12 Month Accelerated Aging<br>12 Month Real Time Aging |
| Inspection | Corrosion Resistance<br>Surface Inspection<br>Tip Curve Retention<br>Dimensional Verification |
| Functional Testing | Pushability/Trackability<br>Sheath Compatibility (Insertion/Withdrawal Force)<br>System Leak (Hemostasis, Luer, Aspiration)<br>Coating Integrity (Particulate, Friction)<br>Radiopacity<br>Needle Actuation<br>Electrical Continuity Pin-Needle |
| Mechanical | Kink Resistance<br>Torque Resistance<br>Tip/Marker band Tensile<br>Sheath to Hemostasis Valve Tensile<br>Shaft to Handle Tensile<br>Needle to Button Tensile<br>Luer to Hypo. Tensile<br>Flushing Tubing to Stopcock Tensile<br>Flushing Tubing to Hemostasis Valve Tensile |
| Electrical | Electrical Safety IEC 60601 |
| Animal Study Comparing to Predicate Device | Access from packaging<br>Visual Inspection<br>Preparation<br>Preliminary Device Function<br>Advancement of Guidewire to Superior Vena Cava |

| Test Type | Test Name |
|---|---|
| | Fluoroscopic Visualization<br>Intracardiac Echocardiographic Visualization<br>Fossa Ovalis Localization<br>Maintenance of component orientation<br>ECG Monitoring<br>Fossa Ovalis Puncture<br>Needle Lumen Function<br>Dilator Crossing of Fossa Ovalis<br>Sheath Crossing of Fossa Ovalis<br>Removal of Device<br>Overall Performance<br>Device Function -Aspirate, Flush, Transduce |

### 5.3.1 Biocompatibility

The Guider Catheter Introducer underwent the following biocompatibility tests as shown in **Table 5.6**. All testing completed passed with the results listed.

**Table 5.6 Biocompatibility Testing Summary**

| Test type | Test name | Result |
|---|---|---|
| **Hemocompatibility** | Hemolysis Test; ASTM F756 Method; Direct Contact and Extract Contact | Pass,<br>Non- Hemolytic |
| | Complement Activation; C3a Assay and SC5b-9 Assay | Pass,<br>Non-Reactive |
| | Platelet and Leukocyte | Pass |
| | Partial Thromboplastin Time (PTT) | Pass, Non-Activator |
| | Prothrombin Time Assay (PT) | Pass |
| **Cytotoxicity** | MEM Elution: L-929 Mouse Fibroblast Cells | Pass,<br>Non-Cytotoxic |
| **Sensitization** | Guinea Pig Maximization (2 extracts) | Pass,<br>Non-Sensitizer |
| **Irritation** | Intracutaneous Reactivity Test (2 extracts) | Pass,<br>Non-Irritant |
| **Pyrogen** | Materials Mediated Pyrogenicity Test | Pass,<br>Non- Pyrogenic |

| Test type | Test name | Result |
|---|---|---|
| **Systemic Toxicity** | Acute Systemic Toxicity Test (Aqueous and Non-Aqueous Extract) | Pass, Non-Toxic |
| ***In vivo* thrombogenicity** | 4-hour Thrombogenicity; 2 canines, Guider and Lancer separately | Pass, Non-Thrombogenic |

**Results**

The Guider Catheter Introducer passed all biocompatibility testing. The full protocols and results for each test are contained in this submission**.**

### 5.3.2 Sterilization

The Guider Catheter Introducer will be offered as sterile to a $10^{-6}$ sterility assurance level (SAL) by an ethylene oxide (EO) sterilization process. The device will undergo EO sterilization at STERIS Isomedix, located at 380 90th Ave NW, Minneapolis, MN 55433. The sterilization protocol conducted by STERIS Isomedix established the procedures for validation of an ethylene oxide sterilization process for this device. The performance qualifications will be executed using the overkill approach as referenced in the international standard, ANSI/AAMI/ISO 11135.

The following tests are conducted to assess the product sterilization:

- Biological Indicator Population Enumeration Testing
- Bioburden Testing
- Product Sterility Testing
- Bacteriostasis/Fungistasis Testing
- Biological Indicator Sterility Testing
- EO Residuals Testing

**Results**

The Sterilization Validation for the Guider Catheter Introducer is pending. The protocol is contained in the submission.

### 5.3.3 Packaging

The Guider Catheter Introducer sets are situated on a high-density polyethylene (HDPE) backer card and are shipped sterile in sealed Tyvek® pouches placed inside a cardboard shelf box and are labeled as single use only. The devices underwent the following distribution and packaging testing:

- Environmental Conditioning
- Distribution Simulation
- Dimensional/Visual Inspection
- Package Integrity/Bubble Test

- Package Integrity/Peel Strength

Prior to the testing, all samples had undergone 2x EO sterilization cycles at STERIS Isomedix. The sterilized units were packaged into shippers. The units/shippers were subjected to environmental conditioning followed by the distribution simulation per ASTM D 4169-09, Distributions Cycle 13; Assurance Level II, and thermal conditioning per ISTA 2A (2011).
Testing was performed by Distribution Dynamic Labs, Inc. (DDL, Inc.) located at 10200 Valley View Road, Eden Prairie, MN 55344.

**Results**
The Guider Catheter Introducer passed all distribution and packaging testing. The full protocols and results for each test are contained in the submission.

### 5.3.4 Shelf Life

The Guider Catheter Introducer will be labeled with a 12-month shelf life. In addition to baseline testing after 2x EO sterilization, environmental conditioning and distribution simulation (T=0), additional devices were subjected to 12-month accelerated aging (T=12aa) and 12-month real- time aging (T=12rt, ongoing at time of submission). The T=12aa test devices were subjected to accelerated aging environmental conditions of 55°C ± 2°C and <20% RH for 38 days to simulate the equivalent of 12 months of real-time aging as guided by ASTM F 1980-07 (2011). The Guider Catheter Introducer passed all baseline and accelerated aging testing while maintaining its sterile barrier.

### 5.3.5 Performance Testing

Mechanical and functional testing of the Guider Catheter Introducer with associated Lancer Integrated Dilator/Transseptal Needle, and associated kit accessories including the guidewire and ECG extension lead wire, were tested post-sterilization: immediately after manufacturing (t=0), after twelve months accelerated aging (t=12aa). Test samples have been manufactured and reserved for testing after twelve months of real-time aging has occurred (t=12rt).

Tests include:

- Product Inspection/Dimensional Verification
- Surface Inspection
- Label Legibility
- Label Adhesion
- Pouch visual inspection
- Sheath Compatibility (Insertion/Withdrawal)
- Pushability/Trackability
- Tip Curve Retention
- System Leak -Liquid Leak and Hemostasis
- System Leak – Luer
- System Leak – Aspiration
- Coating Integrity / Particulate Evaluation
- Coating Integrity / Friction Reduction
- Kink Resistance
- Torque Resistance
- Tip / Markerband Tensile
- Sheath to Hemostasis Valve Tensile
- Shaft to Handle Tensile
- Needle to Button Tensile
- Luer to Hypotube Tensile
- Needle Actuation
- Flush Tubing to Stopcock Tensile
- Flush Tubing to Hemostasis Valve Tensile
- Electrical Safety
- Electrical Continuity Pin-Needle
- Corrosion Resistance
- Package Integrity – Bubble Leak
- Package Integrity – Peel Strength
- Radiopacity

**Results**

All protocol requirements/specifications were met. The full protocols and results for each test are contained in the submission.

### 5.3.6 Animal Study

As part of Design Validation, animal testing was performed at American Preclinical Services, Inc. (APS), located in Minneapolis, MN. APS is USDA registered to conduct research in animals and is AAALAC accredited. All testing followed the requirements for Good Laboratory Practices per 21 CFR 58 as well as ISO 10993 for Biologic Evaluation of Medical Devices.

A single animal study was performed that combined the evaluation of another device cleared under K170373. This was decided due to ethical concerns to limit the number of animals required. This study compared the Guider Catheter Introducer device to the predicate device listed in **Table 5.3**.

**Results**

This study indicates that the Guider Catheter Introducer performed for the selected parameters substantially equivalent to the commercially available St. Jude Medical Swartz™ Braided Transseptal Guiding Introducer (K052644). The full report and results are included in the submission.

## 5.4 Comparison to the Predicate Device

The Guider Catheter Introducer and St. Jude Medical Swartz Braided Transseptal Guiding Introducer are made with similar medical-grade polymers and internal componentry. Both have varying tip geometries. The handles of each also contain a hemostasis valve and sideport tube with stopcock. Each set also includes a vessel dilator and guidewire to facilitate introduction into the vasculature and advancement to the heart.

In order to gain transseptal access to the left side of the heart, the Swartz Braided Transseptal Guiding Introducer requires the use of a separate transseptal needle.

The primary difference with the Guider is that the needle is integrated into the vessel dilator. This allows alignment of components when assembled, a length-matched needle, automatic needle tip retraction within dilator, and the ability to obtain an electrogram from the needle via an ECG adapter. Each of these functions are performed manually with the Swartz Braided Transseptal Guiding Introducer device.

These differences do not impact the intended use.

## 5.5 Summary of Standards Utilized in Testing

The standards used in the testing of the device are outlined in **Table 5.7.**

**Table 5.7 Standards Utilized**

| | Standards No. | Standards Organization | Standards Title | Version |
|---|---|---|---|---|
| 1 | 10993-1 | ISO | Biological Evaluation of Medical Devices | 2009 |
| 2 | 11135-1 | ISO | Sterilization of health care products – Ethylene oxide - Requirements for development, validation, and routine control of a sterilization process for medical devices | 2014 |
| 3 | 10555-1 | ISO | Sterile, Single-Use Intravascular Catheters | 2013 |
| 4 | F2096-11 | ASTM | Standard Test Method for Detecting Gross Leaks in Porous Medical Packaging by Internal Pressurization (Bubble Leak) | 2014 |
| 5 | D4169-14 | ASTM | Performance Testing of Shipping Containers and Systems Distribution Simulation Testing | 2014 |
| 6 | F756-13 | ASTM | Standard Practice for Assessment of Hemolytic Properties of Materials | 2013 |
| 7 | 60601-1:2005/(R)2012 and A1:2012 | AAMI/ANSI ES | Medical electrical equipment - Part 1: General requirements for basic safety and essential performance | 2012 |
| 8 | 11607-1 | ISO | Packaging for Terminally Sterilized Medical Devices - Part 1: Requirements for Materials, Sterile Barrier Systems and Packaging Systems | 2006 |
| 9 | 11607-2 | ISO | Packaging for Terminally Sterilized Medical Devices - Part 2: Validation Requirements for Forming, Sealing and Assembly Processes | 2006 |
| 10 | 14971 | ISO | Medical Device: Application of Risk Management | 2012 |
| 11 | 594-1 | ISO | Conical fittings with 6% (Luer) taper- Part 1: General requirements | 1986 |
| 12 | 594-2 | ISO | Conical fittings with 6% (Luer) taper- Part 2: Lock Fittings | 1998 |
| 13 | F88/F88M-15 | ASTM | Standard Test Method for Seal Strength of Flexible Barrier Materials | 2009 |
| 14 | F2888-13 | ASTM | Standard Test Method for Platelet Leukocyte Count | 2013 |
| 15 | 11135-1:2007 | ISO | Sterilization of Healthcare products – Ethylene oxide – Part 1: Requirements for Development, Validation, and Routine Control of a Sterilization Process for Medical Devices. | 2007 |

| | Standards No. | Standards Organization | Standards Title | Version |
|---|---|---|---|---|
| 16 | 14:2009 | AAMI TIR | Contract Sterilization Using Ethylene Oxide | 2009 |
| 17 | 16:2009(R)2013 | AAMI TIR | Microbiological Aspects of Ethylene Oxide Sterilization | 2013 |
| 18 | 11135-2:2008 | ISO | Sterilization of Healthcare Products – Ethylene Oxide – Part 2: Guidance on the Application of ISO 11135-1 | 2008 |
| 19 | 10993-7:2008(R)2012 | ISO | Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals | 2012 |
| 20 | 10993-04:2002(R)2013 | ISO | Biological Evaluation of Medical Devices - Part 4: Selection of Tests for Interaction with Blood | 2013 |
| 21 | 10993-05:2009 (R)2014 | ISO | Biological Evaluation of Medical Devices - Part 5 Tests for In Vitro Cytotoxicity | 2014 |
| 22 | 10993-11:2006(R)2010 | ISO | Biological Evaluation of Medical Devices - Part 11: Tests for Systemic Toxicity | 2010 |
| 23 | 10993-12 | ISO | Biological Evaluation of Medical Devices - Part 12: Sample Preparation and Reference Materials | 2012 |
| 24 | 10993-10 | ISO | Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Skin Sensitization | 2012 |
| 25 | 13485:2016 | ISO | Medical Devices --Quality Management System—Requirements for Regulatory Purposes | 2016 |
| 26 | F2382-04 | ASTM | Standard Test Method for Assessment of Intravascular Medical Device Materials on Partial Thromboplastin Time (PTT) | 2010 |
| 27 | 11070:2014 | ISO | Sterile Single-use Intravascular Introducers, Dilators and Guidewires | 2014 |
| 28 | F1980-07 | ASTM | Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices | 2011 |
| 29 | F640-12 | ASTM | Standard Test Methods for Determining Radiopacity for Medical Use | 2012 |
| 30 | P2A | ISTA | Packaged Products 150lbs or less | 2011 |
| 31 | 60601-1-2 | IEC | Medical electrical equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests | 2014 |
| 32 | ST72:2011 | ANSI/AAMI | Bacterial endotoxins - Test methods, routine monitoring, and alternatives to batch testing | 2011 |

| | Standards No. | Standards Organization | Standards Title | Version |
|---|---|---|---|---|
| 33 | Chapter 151 | USP | Pyrogen Testing | 2015 |
| 34 | Chapter 161 | USP | Transfusion and Infusion Assemblies and Similar Medical Devices | 2016 |
| 35 | F1886 | ASTM | Standard Test Method for Determining Integrity of Seals for Medical Packaging by Visual Inspection | 2016 |
| 36 | 15223-1 | ISO | Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements | 2016 |

### 5.6 Conclusions

The Guider Catheter Introducer has similar design, materials, and technical requirements as the predicate device. The Guider Catheter Introducer performs as intended, and presents no unacceptable risks to the intended patient population or end user.

The conclusion drawn from the nonclinical tests, summarized in this submission, demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed predicate device listed in **Table 5.3.**

The Guider Catheter Introducer is substantially equivalent to the predicate device, the SJM Swartz Braided Transseptal Guiding Introducer (K052644).